DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Refer to: FEI 1000123364

Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5703

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03-BLT-02

October 17, 2002

WARNING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Maurizio Di Bengino
President
International Gourmet Food
7520A Fullerton Road
Springfield, VA 22153

Dear Mr. Di Bengino,

On September 19, 2002, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 7520A Fullerton Road, Springfield, VA. The inspection was conducted to determine your firm's compliance with FDA's Fish and Fishery Products regulations at Title 21, Code of Federal Regulations, Part 123 (21 CFR 123).

During our inspection, the FDA investigators observed serious deviations from the Fish and Fishery Products regulations. The FDA investigators also provided you with a copy of the Import Seafood HACCP Report (form FDA 3502), which presents their evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

1. Fish or fishery products were obtained from a country that lacked an active memorandum of understanding or similar agreement with FDA, and no adequate written verification procedures were implemented to ensure that these fish and fishery products had been processed in accordance with 21 CFR Part 123. Specifically, your firm failed to have any written verification procedures for any of the fish and fishery products imported, that is to say, no product specifications and no affirmative steps.

2. Failure to employ an individual who has successfully completed appropriate HACCP training, or who is otherwise qualified through job experience.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. We note that FDA documented similar deviations during your last inspection on March 29, 2001. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/ or injunction. In addition, FDA may detain your imported seafood products without examination. Under

such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be made within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Norfolk International Terminal Resident Post, Attention: Edward M. Creech, Jr., Compliance Officer, 7737 Hampton Blvd., Warehouse 4C, Room 206, Norfolk, VA 23505.

If you have questions regarding this letter or the implementation of the HACCP regulation, you may contact Mr. Creech at (757) 441-3787 extension 11.

Sincerely,

Quita Richardson

for Lee Bowers
Director, Baltimore District

cc: Mr. Christopher Walsh
General Manager
International Gourmet Food
7520A Fullerton Road
Springfield, VA 22153